

Improving Readability of Consent Forms: What the Computers May Not Tell You

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The information that is given to the subject or the representative shall be in language understandable to the subject or representative. — DHHS, Section 46.116

The intent of the Department of Health and Human Services' rules is clear. Effecting an understanding on the part of the potential research subject is another matter. Recruiting a research subject is unlike a customary business transaction in which each party has the responsibility for informing him- or herself of the consequences of the transaction (caveat emptor).¹ Instead, the principal investigator has a fiduciary responsibility to insure that the prospective subject fully understands the risks and requirements associated with participation in the study.

The principal document used for educating the subject is the consent form. It is to include all the information the prospective subject needs to know about participation in the study. Unfortunately, this document is often difficult to understand due to the need to include technical information, drug names, and medical terminology.² Sometimes the problem is simply the result of poor writing.

This problem is compounded by the high likelihood that the reader has poor reading skills. Davis and coworkers used the Peabody Individual Achievement Test to show that the reading level of 120 university or community clinic patients was at the 5th-6th grade level-even though these subjects reported completing 10th grade on the average.⁴

It is not possible to estimate accurately a patient's reading ability from his or her appearance or socioeconomic status.⁵ Therefore, investigators are obligated to make a sincere effort to write informed consent documents that can be understood by the maximum portion of the general population.

Several computer software packages allow rapid analysis of readability of texts.⁶ Studies based on this type of analysis have shown that many consent forms require college reading levels or above.⁷ There has been a uniform cry for investigators to make their informed consent documents more readable, but there have been few suggestions how to effect this goal.⁸

To determine what we could do to improve readability of these documents, we examined five consent forms that had been approved by our IRB. Our hypothesis was that readability can be improved by methods other than those addressed by the standard computer-based readability scores.

We scored each document using Correct Grammar (Lifetree Software, Inc., San Francisco, CA) and RightWriter (RightSoft, Inc., Sarasota, FL) computer programs. Both provided Flesch Reading Ease Scores and equivalent grade levels of education needed to understand the document. The Flesch Score uses the number of words in each sentence and the number of syllables per word to assess readability. Correct Grammar also provides an estimate of the fraction of the population that can understand the document and suggestions on how to improve readability. We then edited each document according to the suggestions given by the Correct Grammar program and scored the corrected document.

The third step was to restructure each document with a different physical layout to produce a more graphic version. For example, the texts describing the side effects of drugs and the schedule of clinic visits were replaced with tables or boxes (Figure 1). The typical headings such as "Purpose," and "Side Effects" were eliminated and simple declarative statements served as "titles" for each paragraph. These statements were printed in italics, bold, and 14-point characters as compared to the usual 12-point characters of the text.⁹ For example, the title "Procedure for Randomization" was replaced by "I will not know which drug treatment plan I will receive." The rest of the text remained the same as the computer corrected version. Both computer programs were used to score the readability of the entire text of the graphic version and of the highlighted declarative statements alone.

To obtain a subjective evaluation of suitability, all versions (original, computer corrected, and graphic) of each of the five informed consent documents were distributed to nine scorers. Six scorers were members of our IRB and the other three were members of the Health Center staff who routinely interviewed prospective research subjects. They were requested to rank each version with respect to relative ease of comprehension. We also solicited general comments. The results are shown in Table 1.

According to both the Correct Grammar and RightWriter evaluations, the original versions required the reading level of a college freshman (grade 13). Following the suggestions given by the Correct Grammar program was of little help because the reading level was reduced by less than 1 grade level. The graphic version also required an 11th to 12th grade comprehension level. However, the declarative statements alone were clearly the most readable according to this analysis with a grade level of 8 to 11. The subjective analysis showed a clear preference for the graphic version, which 88 percent of the scorers ranked slightly better or significantly better than the original version.

A complete and objective comparison of the versions would be highly desirable but design of such an evaluation is difficult. For example, results of a general comprehension test given after the subject reads the consent form may reflect the subject's ability to remember relatively unimportant details, such as rare or minor side effects. Conversely, a comprehension test designed to test understanding of only the main ideas would most likely show the graphic version as superior because the main ideas are the ones that are bolded in large italics. This is not to say that a valid objective test would not be possible, but it would require a considerable investment of time and would most likely reveal what the scorers recognized immediately. That is, use of a more graphic presentation of information is more likely to improve comprehension.

An additional advantage of the graphic version is that the format may provide a better forum for discussion during the recruitment session. Interviewers usually focus on the major points before presenting the entire consent form. The graphic version supports and reinforces the recruiter's presentation rather than competing with it.

The comments received from our nine scorers were generally very favorable and several scorers had additional suggestions as to how to improve readability and comprehension. For example, one suggested putting the name of the physician conducting the study, to whom questions could be addressed, in bold type. This could improve the likelihood that the subject would remember this important information. Various other helpful comments show that given the opportunity to be creative, almost anyone can make improvements in the consent form. These improvements most likely would not be revealed by a computer-based readability analysis.

In summary, we believe that informed consent documents can be greatly improved by employing methods that are neither suggested nor detected by computer-based readability scores. The computer programs can be helpful for improving sentence structure. However, the easiest and greatest improvement in readability and comprehension may come from the use of graphics and the use of simple declarative summary statements as headings for each paragraph. Investigators writing informed consent documents could follow this format if they were given an example and were encouraged to be creative. Digesting a complex informed consent document into several simple statements of the main ideas may require some extra thought on the part of the investigators. However, we believe the benefits to the subjects and to clinical research as a whole more than justify the effort.

References

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Figure 1
The University of Texas Health Center at Tyler
Informed Consent
Beta-Carotene/Retinol and Lung Cancer Chemoprevention Study

My doctors have asked me to participate in a study of medicines to prevent lung cancer.

I, _____, understand that I have been asked to participate in a research project because my doctors believe that I have an increased risk of developing a lung tumor. I am at an increased risk because I have worked around asbestos and /or have smoked cigarettes or already have some abnormalities in my sputum (phlegm). I understand that right now there are no known ways of decreasing the risk of lung cancer except to stop smoking.

The study will provide two medicines that may prevent lung tumors.

My doctors have told me that scientists at the University of Texas Health Center at Tyler (UTHCT) and other institutions in the United States are working hard to find a medicine that will prevent lung tumors from developing. Two possible medicines are beta-carotene (a material found in carrots and other vegetables) and retinol (Vitamin A found in meat). These drugs are now being tried in humans to prevent lung tumors but the potential for success is unknown. However, doctors know beta-carotene to be a safe medicine because patients with a particular kind of blood disease have been taking it for years with few bad effects.

The study will compare these drugs with a placebo.

The purpose of this research project is to compare beta-carotene and retinol with a placebo (drug with no known effect) to see if beta-carotene and retinol are more effective than the placebo in preventing the development of lung tumors.

I will need to take the medicine daily for three years.

The study will last for about 3 years. As a participant in the study, I agree to take the assigned medicine. I will be taking either beta-carotene daily and retinol every other day or a placebo daily. My doctors will not tell me which one I am taking until the end of the study.

I will need to come to the clinic every six months for a visit.

I understand that I will need to come to the clinic for tests at the beginning of the study, again at six weeks, and then every six months for three years. During the clinic visits, my doctors will draw about one ounce of blood and collect my sputum (phlegm) for testing. Every three months between clinic visits, my doctors will ask me to collect my sputum and mail it to the clinic for testing.

Schedule

Date	Type of Visit	Samples
Start	Clinic	blood, sputum
Six Weeks Later	Clinic	blood, sputum
Every 3 Months	Mail	sputum
Every 6 Months	Clinic	blood, sputum

There may be some side effects to the drugs.

My doctors consider the dosages I will be taking (50mg beta-carotene per day and 25000 IU retinol every other day) to be safe and I should not expect any serious side effects. My doctors have explained to me that a slight yellowing of the skin may occur from the pills I take. The yellowing will go away when the medicine is stopped. Sometimes slight nausea or diarrhea may occur. At very high doses (much higher than I will be taking) retinol can be toxic.

Signs and symptoms of retinol toxicity include:

dry skin	swollen, cracked lips
itching	rash
bleeding gums	hair loss
swelling of extremities	bone and joint pain
headache	dizziness
blurred vision	loss of appetite
loss of sex drive	changes in the blood such as anemia
weakness and fatigue	enlarged liver and spleen
	increased pressure inside the skull

The procedure involves slight discomfort.

My doctors have told me that these are extreme conditions caused by excessive doses and that they will monitor me closely for such conditions throughout the clinical trial. My doctors will take me off the medicine immediately if any serious problems occur. The symptoms usually go away soon after medication is discontinued.

I understand that I may get a bruise on my arm when my blood is drawn and that I may experience coughing or nausea when I use the breathing machine (ultrasonic nebulizer that makes a salty mist) to help collect my sputum. These are the only risks involved in the procedures.

Table 1. Summary of Objective and Subjective Ratings of Different Versions of Five Consent Form

	Original Version	Computer Edited Version	Graphic Version	Headings of Graphic Version
Grade Level (Correct Grammar)	13.0 ± 1.8	12.4 ± 1.6	12.6 ± 1.0	10.6 ± 1.9
Grade Level (RightWriter)	13.0±1.6	12.3±1.0	11.5±1.0	7.8±1.5
% Understanding (Correct Grammar)	42 ± 22	52 ± 22	48 ± 12	68 ± 17
Subjective:				
Sig. Worse		0	11 ± 0%	
Slight Worse		2 ± 4%	0	Not
No Difference	100%	18± 12%	4 ± 6%	Applicable
Slight Better		80± 14%	16 ± 10%	
Sig. Better		0	72 ± 12%	

The values listed are the means and standard deviations for the five consent forms.

Subjective values are the average number of scorers designating each subjective category, expressed as a percent of the nine scorers.

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